

**Rational Pharmaceutical Management Plus**  
***Technical Assistance to the DOTS Plus Program-Moldova: Trip***  
**Report**

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Robert Burn

March 2005

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### **About RPM Plus**

The Rational Pharmaceutical Management Plus (RPM Plus) Program, funded by the U.S. Agency for International Development (cooperative agreement HRN-A-00-00-00016-00), works in more than 20 developing countries to provide technical assistance to strengthen drug and health commodity management systems. The program offers technical guidance and assists in strategy development and program implementation both in improving the availability of health commodities—pharmaceuticals, vaccines, supplies, and basic medical equipment—of assured quality for maternal and child health, HIV/AIDS, infectious diseases, and family planning and in promoting the appropriate use of health commodities in the public and private sectors.

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### **Abstract**

Tuberculosis is a growing health issue in Eastern Europe and an inexpensive and effective treatment regimen exists promulgated by World Health Organization. The United States Agency for International Development is funding Rational Pharmaceutical Management Plus (RPM Plus) to strengthen the drug management aspects of national tuberculosis control programs (NTP). RPM Plus assessed drug management information needs for program managers of the Moldova national tuberculosis program in 2002. Following a policy options workshop (April 2003) a set of drug management indicators was established to facilitate monitoring of the supply system, a sub-set of which are being incorporated into the monitoring and evaluation system of the Ministry of Health (MOH). RPM Plus, through its local consultant is working with the NTP to develop data collection forms and procedures for these indicators. In 2004, RPM Plus initiated technical assistance in pharmaceutical management for 2<sup>nd</sup>-line drugs, to complement the MOH's application to the Green Light Committee for support with the implementation of a DOTS Plus program to treat multi-drug resistant tuberculosis (MDR-TB) patients. This assistance includes the development with the NTP of a patient package distribution mechanism for MDR-TB cases, in order to ensure effective inventory control and use of 2<sup>nd</sup>-line anti-TB medicines.

### **Recommended Citation**

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### **Key Words**

Tuberculosis, national tuberculosis program, tuberculosis drugs, drug management information system, DOTS Plus, Moldova.

## Contents

Acronyms.....	v
Background .....	1
Purpose of Trip .....	1
Scope of Work .....	1
Activities.....	3
Collaborators and Partners.....	6
Adjustments to Planned Activities and/or Additional Activities .....	6
Next Steps.....	9
Immediate Follow-up Activities .....	9
Recommendations .....	9
Agreement or Understandings with Counterparts.....	9
Important Upcoming Activities or Benchmarks in Program .....	9
Annex 1:Persons met .....	11
Annex 2: Request for Country Clearance .....	13
Annex 3: Proposed timeframe for development and implementation of DOTS	
PLUS Patient Package.....	17



## ACRONYMS

AIHA	American International Health Alliance
DMIS	Drug Management Information System
DOTS	Directly Observed Therapy Short-course (WHO TB Control Strategy)
DOTS Plus	WHO Strategy for multi-drug resistant tuberculosis
E&E	Europe and Eurasia (Bureau of USAID)
GDF	Global Drug Facility
GFATM	The Global Fund to Fight AIDS, Tuberculosis & Malaria
GLC	Green Light Committee
M&E	Monitoring and Evaluation
MDR-TB	Multi-Drug Resistant Tuberculosis
MOH	Ministry of Health
MSH	Management Sciences for Health
NGO	Non-governmental organization
NTP	National Tuberculosis Control Program
PCU	Project Coordination Unit
RPM Plus	Rational Pharmaceutical Management Plus Program [MSH]
SPCPHSM	Scientific Practical Center of Public Health and Sanitary Management
TA	Technical Assistance
TB	Tuberculosis
USAID	United States Agency for International Development
WHO	World Health Organization



## **BACKGROUND**

Moldova has one of the highest rates of tuberculosis (TB) within the former Republics of the USSR. With assistance from the World Health Organization (WHO), the Stop TB Initiative and the United States Agency for International Development (USAID), the Ministry of Health (MOH) established a DOTS program in 2002. One of the five pillars of the WHO DOTS strategy for TB control is “uninterrupted supply of quality assured drugs”.

Management Sciences for Health’s (MSH) Rational Pharmaceutical Management Plus (RPM Plus) Program is working with the National Tuberculosis Control Program (NTP) to strengthen the drug management information system (DMIS) for first line anti-TB drugs, including identifying a set of pharmaceutical indicators to be implemented by the NTP and which will contribute directly to the MOH’s health statistics monitoring and evaluation (M&E) system.

In July 2004, the Ministry of Health applied to the Green Light Committee (GLC) of the WHO for support to a DOTS Plus project to treat multi-drug resistant TB cases. During technical assistance activities in FY03, RPM Plus applied the concept of a patient package to the management of pharmaceuticals for the treatment of MDR-TB cases, resulting in the MOH’s application to the Green Light Committee, including the introduction of such a system. The benefits will be a secure, reliable and centrally controlled procedure for the distribution of 2<sup>nd</sup>-line drugs to patients during the lengthy, out-patient, continuation phase of MDR-TB treatment. RPM Plus is working closely with the NTP and the MDR-TB department, both located within the Institute of Phthisiopneumology in Chisinau, to determine the operational requirements for this system, and to provide appropriate technical assistance.

### **Purpose of Trip**

Robert Burn, Senior Program Associate and manager of the RPM Plus Moldova portfolio visited Chisinau to respond to developing needs for technical assistance (TA) in drug management for the DOTS Plus and DOTS projects in the areas of quantification, procurement and distribution.

### **Scope of Work**

- Brief/debrief the USAID Mission on the RPM Plus Program activities in Moldova
- Work with RPM Plus local consultant to specify priorities for TA in support of DOTS Plus project initiation and the DOTS project transition to local procurement

- Formulate proposals for distinct support activities in conjunction with counterparts
- Draw a schedule to implement agreed activities and establish resources needed to support the local consultant.

The list of persons met and the Request for Country Clearance are attached as annexes (1 and 2 respectively).



## ACTIVITIES

1. Brief/debrief the USAID Mission on the RPM Plus Program activities in Moldova.

Robert Burn and Rita Seicas, MSH/RPM Plus consultant in Moldova met with Diana Cazacu, Program Assistant, USAID to discuss progress. Ms. Cazacu was apprised of the ongoing technical assistance RPM Plus has been providing to support of the DOTS Plus project in Moldova which had recently received the approval of the Green Light Committee. RPM Plus has assisted the NTP and the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) Project Coordination Unit (PCU) with the quantification of 2<sup>nd</sup>-line pharmaceuticals and also medicines to address adverse reactions. The NTP had been advised to finalize the procurement arrangements with the GLC soonest since the time required to establish the financial links and the lead-time for the delivery of the medicines meant that the process needed to be initiated as soon as possible in order to have the drugs delivered by the planned commencement date of the DOTS Plus project (June 2005).

The RPM Plus team also informed USAID about the outcomes of the meetings held with counterparts during the visit, the details of which are contained in the following paragraphs.

2. Work with RPM Plus local consultant to specify priorities for TA in support of DOTS Plus project initiation and the DOTS project transition to local procurement

Firstly, Ms. Seicas updated Mr. Burn on personnel changes affecting the national tuberculosis control program:

- Dr Sofronie had been appointed to the position of Head of the Institute of Phthisiopneumology replacing Dr. Timbalaru who would continue to work within the Institute as the head of the Diagnostic Department.
- Dr. Dumitru Sain, who had temporarily acted as the NTP Coordinator, following the move of Dr. Victor Burinschi to join the GFATM Project Coordination Unit, had been confirmed in this position.
- Dr Ana Donica was recently appointed to be chief of the MDR-TB department at the Institute of Phthisiopneumology.

### Drug Management Indicators

The RPM Plus team discussed the forthcoming distribution of the report of the workshop held in November 2004 on the crafting of drug management indicators to monitor the performance of the NTP in managing the supply of 1<sup>st</sup>- and 2<sup>nd</sup>-line medicines. Ms. Seicas continued to support the incorporation of a sub-set of these indicators into monitoring and evaluation software being developed by the

MOH, at the Scientific Practical Center for Public Health and Sanitary Management (SPCPHSM), by liaising with SPCPHSM and the private companies preparing the software specifications and the computer application.

The preparatory work for the Drug Management Indicator workshop (November 2004) and the conclusion of the meeting confirmed that all the data to operationalise the monitoring indicators was not available. RPM Plus will continue to work with the NTP, building on existing practice and with the SPCPHSM system in mind, to develop appropriate reporting forms and data collection and analysis procedures.

### **Patient Package Scheme for MDR-TB treatment**

The Green Light Committee confirmed approval of the DOTS Plus project in Moldova during the visit. The NTP, in collaboration with the GFATM Project Coordination Unit has been preparing estimations of the quantities of drugs required for the initial cohort of MDR-TB patients. The GFATM project is the source of funding for the purchase of 2<sup>nd</sup>-line medicines through the GLC mechanism for concessionary pricing of high quality products. Ms. Seicas, with assistance from technical staff at RPM Plus, assisted in the quantification of requirements. It was expected that the project would commence in June following the delivery of the necessary drugs. In order for the proposed patient package scheme to be initiated RPM Plus will collaborate closely with the NTP to finalise the definition of the operation of the scheme and the instructions for its implementation. Subsequently, appropriate staff will be trained in the operation of the scheme.

### **Procurement**

Moldova has received three years' support from the Global Drug Facility in the form of first-line anti-TB medicines and is starting to transition from this grant to locally financed and managed procurement. Existing stocks of 1st-line medicines are estimated to be sufficient to meet needs until September 2005. The GFATM project has funding to procure 1st-line drugs and the NTP and GFATM PCU have begun to preparations to use the Global Drug Facility direct procurement mechanism. As necessary, RPM Plus can assist with the quantification of 1st-line medicines (with one possibility being the introduction of the Quantimed estimation tool developed by MSH).

### **Training**

RPM Plus proposes to assess the need for drug management training for TB physicians at raion level, with a view to providing appropriate training in the future.

3. Formulate proposals for distinct support activities in conjunction with counterparts

RPM Plus met with Dr. Sofronie, recently appointed Head of the Institute of Phthisiopneumology. This meeting was used to explain the RPM Plus program of activities in Moldova and to begin a dialogue on the immediate areas of RPM Plus support for the NTP. Dr. Sofronie was enthusiastic about continuing the collaboration. He informed RPM Plus about a recent government tender for essential medicines, the order prepared by the NTP for 1<sup>st</sup> and 2<sup>nd</sup> line medicines, which the MOH reduced the budget for (possibly through concern about the pending GLC approval of the DOTS Plus project and the procurement of drugs thereafter through the GLC mechanism).

Dr. Sofronie advised that the MDR-TB Department at the Institute had been officially established and a team with responsibility for treatment and observation organized. Ensuring the supply of 2<sup>nd</sup>-line medicines, for in-patients and out-patients, was one main responsibilities of the department.

Dr. Sofronie was eager to establish a structure and procedures at the NTP/Institute to better coordinate and manage the medicines for DOTS and DOTS Plus programmes. RPM Plus responded by offering to assist in the establishment of a *Drug Management Team* by elaborating terms of reference for the group and this was welcomed by him.

RPM Plus was informed officially that Dr. Sain had been re-appointed to the position of Coordinator of the National Tuberculosis Control Programme and subsequently met with him to discuss immediate joint steps to implement the patient package scheme outlined in the GLC application and the development of the just proposed drug management team. It was agreed that the RPM Plus team would meet later that week with the staff of the Institute who would likely comprise the Drug Management Team.

At this meeting, attended by Dr. Dumitru Sain, Dr. Ana Donica, Dr. Valeru Crudu, Dr Ecaterina Axenti, and Dr. Alina Pascaru, RPM Plus discussed the formation of the Drug Management Team for DOTS and DOTS Plus programs and outlined the terms of reference (prepared by RPM Plus during the visit) which would incorporate the responsibilities of the team. The issue of a “team leader” was raised and Dr. Sain said he would discuss this further with Dr. Sofronie. RPM Plus advised that a team leader should have an overall understanding of all drug management issues for both DOTS and DOTS Plus programs.

Dr. Crudu proposed that there was a need for an easily completed format to be developed which would facilitate the monitoring of stock levels of anti-TB medicines at the raion level by the team (RPM Plus is already working on this). Dr. Sain raised issues about the status, responsibilities, remuneration of TB

doctors at the raion level, though this is not an area RPM Plus is likely to be able to advise on.

In connection with the drug management indicators and the computerized national monitoring system it was mentioned that the American International Health Alliance (AIHA) project would be staging a four day training in the autumn for the raion staff who will have the task of entering data into the system.

4. Draw a schedule to implement agreed activities and establish resources needed to support the local consultant.

Following the various meetings with counterparts the RPM Plus team determined a schedule for activities to prepare for the implementation of the patient package scheme, based on the expected commencement date of June 2005. These are contained in annex 3.

### **Collaborators and Partners**

Dr. Sofronie, Director National Institute of Phthisiopneumology  
Dr. D. Sain, Coordinator National Tuberculosis Control Program  
Dr. D. Laticevschi, Project Manager, GFATM PCU  
Ms. R. Seicas, consultant

### **Adjustments to Planned Activities and/or Additional Activities**

RPM Plus met with the Project Manager and the Monitoring and Evaluation Officer of the Project Coordination Unit of the GFATM TB/AIDS Project in Moldova to discuss procurement issues relating to 1<sup>st</sup> and 2<sup>nd</sup>-line medicines. The GFATM project is financing both sets of medicines.

For 1<sup>st</sup>-line medicines, existing GDF grant supplies should last till September. The M&E officer had quantified 1<sup>st</sup>-line medicine needs using the established GDF estimation spreadsheet and basing the calculation on 6,000 patients. The MOH and the PCU need to formalize their relationship and GFATM project funding would be available in May if an agreement is signed in March. The GFATM had been researching the process for direct procurement with the GDF and estimated that it would take 4-5 months to complete the financial and other arrangements and for delivery. Dr. Burinschi was working closely with the NTP on the product specification (eg. use of FDCs and blister packaging).

The contract between MSH and Rita Seicas expires on March 31<sup>st</sup> 2005. In order to ensure that MSH was in compliance with local employment legislation when renewing the consultancy, RPM Plus Senior Program Associate, R. Burn,

consulted with Dr. Laticevschi and Mr. Viorel Soltan, AIHA Project Director, for information on employment legislation and sources of legal opinion.



## **NEXT STEPS**

### **Immediate Follow-up Activities**

1. Finalise draft of the terms of reference for the Drug Management Team and share with Dr. Sofronie, Head, Institute of Phthisiopneumology.
2. Prepare a covering letter and distribute the Report on TB Drug Management Indicator Working Group Meeting of 18<sup>th</sup> November 2004, Chisinau, Moldova, to all participants.
3. Draft the full description of the patient package distribution scheme for 2<sup>nd</sup>-line drugs for MDR-TB treatment and prepare comprehensive instructions, in collaboration with members of the Drug Management Team.

### **Recommendations**

No specific recommendations.

### **Agreement or Understandings with Counterparts**

RPM Plus will support the establishment of the Drug Management Team within the Institute of Phthisiopneumology, including consideration of training activities for team members in selected aspects of pharmaceutical management. Following review of the draft terms of reference for the Drug Management Team, Dr. Sofronie would take the appropriate steps to formally institutionalize the Team within the Institute.

### **Important Upcoming Activities or Benchmarks in Program**

RPM Plus will participate in the Global Drug Facility Third Year In-country Monitoring Visit in April to review the Moldovan National Tuberculosis Control Program's compliance with the terms and conditions of the GDF grant of 1<sup>st</sup>-line drugs.





## ANNEX 1: PERSONS MET

Persons met during TDY	
Organisation	Name and Position
National Tuberculosis Control Programme/ Institute of Phthisiopneumology	Dr. S. Sofronie, Head Institute of Phthisiopneumology Dr. Sain, Manager National Tuberculosis Control Program Dr. Valeru Crudu, Head Laboratory Services Dr. Ana Donica, Chief MDR-TB Department Dr. Alina Pascaru, Monitoring and Evaluation Department
Project Coordination Unit, GFATM TB/AIDS Project in Moldova	Dr. Dumitru Laticevschi, Project Manager Dr. Victor Burinschi, Monitoring and Evaluation Specialist
USAID	Ms. Diana Cazacu, Project Management Assistant
MSH/RPM Plus Consultant	Ms. Rita Seicas



## ANNEX 2: REQUEST FOR COUNTRY CLEARANCE

TO: Vasile Filatov, USAID/Moldova

FROM: Management Sciences for Health (MSH) Rational Pharmaceutical Management Plus (RPM Plus) Program

SUBJECT: Travel of MSH/RPM Plus Senior Program Associate Robert Burn to Chisinau, Moldova from February 24 to March 4, 2005. RPM Plus Cooperative Agreement No.: HRN-A-00-00-00016-00

COPY: Anthony Boni/ Global HSPR/CTO RPM Plus  
Kama Garrison/ USAID Washington  
Delna Ghandhi/ USAID E&E Bureau  
Veronica Mihailiuc, USAID/Moldova  
Diana Cazacu, USAID/Moldova  
Mark Levinson, USAID/Moldova  
Olena Radziyevska, USAID/Ukraine  
Douglas Keene, Director, MSH/RPM Plus Program  
Maria Miralles, Deputy Director, MSH/RPM Plus Program  
Andrey Zagorskiy, Project Manager for TB, MSH/RPM Plus Program

Program Robert Burn, Senior Program Associate, MSH/RPM Plus Program

1. The RPM Plus Program requests country clearance for MSH/RPM Plus Senior Program Associate Robert Burn to Chisinau, Moldova from February 24 to March 4, 2005.

### 2. **Background:**

Moldova has one of the highest rates of tuberculosis (TB) within the former Republics of the USSR. With assistance from the World Health Organization (WHO), the Stop TB Initiative and USAID, the Ministry of Health (MOH) established a DOTS program in 2002. In July 2004, the Ministry of Health applied to the Green Light Committee (GLC) of the WHO for support for a DOTS Plus project to treat multi-drug resistant TB cases.

RPM Plus has been working with the National Tuberculosis Control Program to strengthen the drug management information system (DMIS) for first line anti-TB drugs, including identifying a set of pharmaceutical indicators to be implemented within the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) project's monitoring and evaluation (M&E) system.

During technical assistance activities in FY03, RPM Plus applied the concept of a patient package of anti-TB drugs to the management of pharmaceuticals for the treatment of MDR-TB cases, resulting in the MOH's application to the Green Light Committee, including the introduction of such a system. The benefits will be a secure, reliable and centrally controlled procedure for the distribution of 2<sup>nd</sup>-line drugs to patients during the lengthy, out-patient, continuation phase of MDR-TB treatment. RPM Plus is working closely with the central unit of the NTP and the MDR-TB department, both located within the Institute of Phthisiopneumology in Chisinau, to determine the operational requirements for this system, and to provide appropriate technical assistance.

Moldova has received three years' support from the Global Drug Facility in the form of first-line anti-TB medicines and will need to transition from this grant to locally financed and managed procurement.

### **3. Purpose of Proposed Visit:**

Respond to developing needs technical assistance in drug management for the DOTS Plus and DOTS projects in the areas of quantification, procurement and distribution.

### **4. Scope of work for Robert Burn for this visit is as follows:**

For the RPM Plus/Moldova program:

- Brief/debrief the USAID Mission on the RPM Plus Program activities in Moldova
- Work with RPM Plus local consultant to specify priorities for TA in support of DOTS Plus project initiation and the DOTS project transition to local procurement
- Formulate proposals for distinct support activities in conjunction with counterparts
- Draw a schedule to implement agreed activities and establish resources needed to support the local consultant.

### **5. Anticipated contacts:**

Mr. Vasile Filatov (USAID/Moldova); Dr. Turcanu, First Vice Minister and other officials and specialists from the Moldovan Ministry of Health; Dr. Sain, (National TB Program); Dr. Sofroni, (Institute of Phthisiopneumology); Ms. Rita Seicas, MSH consultant, Dr. Dumitru Laticevschi, GFATM, and Mr. Viorel Soltan, Project Director, AIHA.

## **6. Logistics:**

Robert Burn will arrive in Chisinau on Thursday, February 24, 2005 and depart Moldova on Friday, March 4, 2005. No Mission assistance is required.

## **7. Funding:**

The in-country RPM Plus work will be paid for with USAID/Moldova Mission and E&E Regional funds.

## **8. Action:**

Please advise Anthony Boni of country clearance for Robert Burn to travel to Moldova as planned. Please reply via e-mail to the attention of Anthony Boni, USAID/G/PHN/HN/HPSR tel. (202) 712-4789, fax (202) 216-3702, e-mail address [aboni@usaid.gov](mailto:aboni@usaid.gov). Please send carbon copies to Kama Garrison at [kgarrison@usaid.gov](mailto:kgarrison@usaid.gov), Andrey Zagorskiy at [azagorskiy@msh.org](mailto:azagorskiy@msh.org), Robert Burn at [rburn@msh.org](mailto:rburn@msh.org), Douglas Keene at [dkeene@msh.org](mailto:dkeene@msh.org) and Meriel Jimenez at [mjimenez@msh.org](mailto:mjimenez@msh.org).

Thank you in advance for Mission cooperation.



### **ANNEX 3: PROPOSED TIMEFRAME FOR DEVELOPMENT AND IMPLEMENTATION OF DOTS PLUS PATIENT PACKAGE**

Proposed Date	Activity/Action	RPM Plus	NTP
March 2005	Terms of Reference for DOTS PLUS Drug Management Team drafted	RS/RB	
March 2005	Terms of Reference for DOTS PLUS Drug Management Team finalized		DOTS PLUS Drug Management Team
March 2005	Patient package scheme drafted for review	RB and RS	
March 2005	Draft patient package scheme reviewed and commented on by NTP		DOTS PLUS Drug Management Team
March 2005	Completion of patient package scheme: operations	RS	DOTS PLUS Drug Management Team
March 2005	Completion of patient package scheme: data collection and reporting formats	RS	DOTS PLUS Drug Management Team
April 2005	Completion of patient package scheme: instructions	RS	DOTS PLUS Drug Management Team
April 2005	Ministerial Order prepared		DOTS PLUS Drug Management Team
April 2005	Preparation of training materials & event	RS/RB	
April 2005	Training of staff at MDR-TB department & pharmacy	RS	DOTS PLUS Drug Management Team
1 June 2005	Patient package system implementation		DOTS PLUS Drug Management Team

## Drug Management for Medicines for Adverse Reactions

Proposed Date	Activity/Action	RPM Plus	NTP	PCU GF Project
Feb 2005	Development of catalogue of needed medicines		NTP management Chief MDR-TB Dept.	
31 Mar 2005	Quantification of requirements (Incorporating proportion of patients experiencing each adverse reaction)	RS	NTP management Chief MDR-TB Dept.	VB
31 Mar 2005	Estimation of initial order quantities	RS	NTP management Chief MDR-TB Dept.	VB
15 Apr 2005	Estimation of budget and identification of funding sources		NTP management Chief MDR-TB Dept.	VB
30 Apr 2005	Specification of items and documentation for procurement of initial requirements	RS	NTP management Chief MDR-TB Dept.	LI
31 Mar 2005	Establish procurement timeline through IDA (from order to receipt) Determine deadline for placement of initial order.		NTP management Chief MDR-TB Dept.	VB/LI
31 Mar 2005	Formal order instruction from NTP on PCU NTP/PCU relationship documented		NTP management Chief MDR-TB Dept.	
??	Initial order placed			LI
Jun 2005	Identification, prescription, management of adverse reactions practice	RS	NTP management Chief MDR-TB Dept.	
May 2005	Development of consumption-based estimation of requirements process Documentation Recording forms Process Monitor consumption against stock	RS	NTP management Chief MDR-TB Dept. Chief Pharmacist	



June-Dec 2005	Monitoring consumption		NTP management Chief MDR-TB Dept. Chief Pharmacist	
4 months after start of treatments	Consumption-based estimation of second procurement quantities	RS	NTP management Chief MDR-TB Dept.	VB
Jul 2005	Establish timeline for second and subsequent orders	RS	NTP management Chief MDR-TB Dept. Chief Pharmacist	LI



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